



UNITED STATES DEPARTMENT OF COMMERCE

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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/477,984	07/95	COWGILL	C 1087.001

EXAMINER

TOLZEAU

ART UNIT

PAPER NUMBER

1811

12

DATE MAILED: 12/23/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS*Supplemental*☒ This application has been examined ☐ Responsive to communication filed on 9-3-96
11-5-96
10-29-96 ☐ This action is made final.A shortened statutory period for response to this action is set to expire 30 month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-46 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-46 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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15. Claims 1-46 are present in the instant application. Claims 25-46 have been added in the amendment received in this Office 9/3/96. A Supplemental Information Disclosure Statement has been received in this Office on 10/29/96.

Restriction to one of the following inventions is required under 35 U.S.C.

5 § 121:

I. Claims ¹⁻¹⁸~~1-8~~, drawn to a method for producing properly folded insulin-like growth factor (IGF) polypeptides from a yeast cell, classified in Class 435, subclass 71.2.

10 II. Claims 19-25, drawn to methods of refolding polypeptides comprising denaturing and renaturing, classified in Class 530, subclass 407+.

III. Claims 26-27 ~~and 40~~, drawn to an IGF composition whose overall purity is about 95-97%, classified in Class 514, subclass 3.

15 IV. Claims ²⁸⁻⁴⁶~~28-39 and 41-46~~, drawn to a process for purifying IGF-1 using r-HPLC at a pH of 6-8 containing an alcoholic or aprotic solvent, classified in Class 530, subclass 380+.

The inventions are distinct, each from the other because of the following reasons:

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Invention 1 does not require the specifics of invention II nor does Invention II require the specifics of invention I. Invention III does not require the specifics of invention IV nor does invention IV require the specifics of invention III. Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case, invention III is an IGF-1 that can be made through recombinant DNA technology. In invention, IV, purified peptides can also be made through recombinant DNA technology. The two are drawn to patentably distinct methods that have acquired a separate status in the art as shown by their different classification, have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one invention is not required for another invention, thusly the restriction for examination purposes as indicated is proper.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

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accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any communication regarding this application should be addressed to P. Lynn Touzeau, Ph.D., whose telephone number is (703)308-3965.

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12-16-96

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